Polymorphous forms of rosiglitazone maleate

FIELD OF THE INVENTION

The present invention relates to the synthesis and characterization of three polymorphous forms of rosiglitazone maleate.

STATE OF THE ART

Rosiglitazone is a molecule of thiazolidinedione structure which forms part of the class of antidiabetics. Its structure formula is given below.

US 5,002,953 describes for the first time the compound and its use as an antihyperglycaemic. In that patent all its pharmaceutically acceptable salts are also claimed.

US 5,741,803 instead specifically describes the maleate of rosiglitazone, shown below, stating that among the possible salts, the maleate exhibits particularly favourable characteristics of stability and solubility in water.

In that patent, two examples of the preparation of the salt in question are given. In the first example the compound is prepared by hot dissolution of the rosiglitazone base mixed with maleic acid, and slow